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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,711	11/02/2005	Jose Luis Castro Pinciro	T1627P	9718
210 7590 02/01/2008 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
			EXAMINER HUYNH, CARLIC K	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 02/01/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,711	<b>Applicant(s)</b> PINEIRO, JOSE LUIS CASTRO	
	<b>Examiner</b> Carlic K. Huynh	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 11, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02 November 2005</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 9-16 are pending in the application, with claim 16 having been withdrawn from consideration, in response to the restriction requirement submitted on October 9, 2007. It is noted that claims 1-8 were cancelled in a Preliminary Amendment filed on November 2, 2005. Accordingly, claims 9-15 are being examined on the merits herein.

### ***Election/Restrictions***

2. Applicant's election without traverse of the claims of Group I, namely claims 9-15, in the reply filed on November 13, 2007 is acknowledged.

Claim 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on November 13, 2007.

3. Applicants' election of: (1) UK-333774 as the species of a glycine/NMDA antagonist; (2) aprepitant as the species of a tachykinin NK-1 antagonist; and (3) neurodegeneration that results from stroke as the species of a neurodegeneration, in the reply filed on November 13, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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Claims 11 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Election was made without traverse in the reply filed on November 13, 2007.

Accordingly, claims 9-10 and 12-14 are being examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

### ***Information Disclosure Statement***

The Information Disclosure Statement submitted on November 2, 2005, is acknowledged.

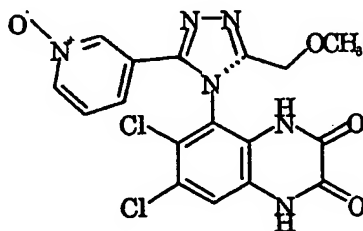
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

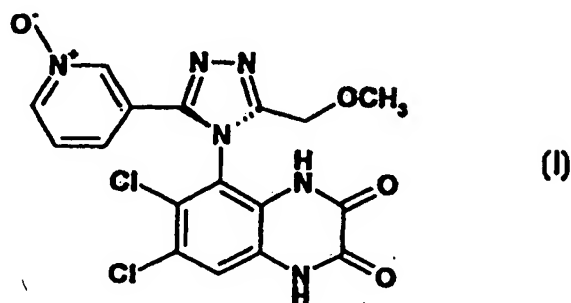
4. Claims 9-10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stobie et al. (WO 98/38136 as cited in the IDS) or Norman (IDrugs, 1 April 2003, Vol. 6, No. 4, pp.297-301) in view of Burgey et al. (US 2004/0229861).

It is noted that UK-333747 is known in the art as,



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Stobie et al. teach a quinoxalinedione compound of formula (I),



is an NMDA antagonist and that NMDA antagonist have been known in the art for treating neurodegenerative disorders arising from events such as stroke, transient ischemic attack, peri-operative ischemia, and global ischemia (abstract; and page 1, lines 25-27).

Norman teaches that UK-333747 can be used for the clinical treatment of stroke (page 299).

Neither Stobie et al. nor Norman teach aprepitant.

Burgey et al. disclose that treating ischemia and stroke with CGRP antagonists are known in the art (page 1, paragraph [0004]). The compositions of Burgey et al. are CGRP antagonists that may be used in combination with a NK-1 receptor antagonist such as aprepitant (page 15, paragraph [0420]).

Accordingly, absent the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Stobie et al. to contain aprepitant because the compounds of Burgey et al. are aprepitant and according to Burgey et al., aprepitant can be used to treat stroke.

The motivation to combine the compounds of Stobie et al. to the compounds of Burgey et al. is that the compounds of Burgey et al. are aprepitant and that such compositions treat stroke.

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It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

### ***Conclusion***

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SABINA QAZI, PH.D  
PRIMARY EXAMINER

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ckh